REMARKS

Claims 1-24 and 27-29 are pending in the application.

Claims 1-10, 19, 20 and 27 stand rejected under 35 USC § 112, first paragraph, as failing to comply with written description requirement, as the Examiner states that the Specification does not support for the limitation "an outer surface that defines an outer diameter that is at least four times a radial wall thickness of said cap at said engagement portion." Claims 1 and 19 have been amended to indicate that the claimed ratio is at least approximately five times. This is supported in the Specification as follows. With an outer diameter E of 0.110, and an inner diameter G of 0.067 inch, a radial wall thickness of (0.110 - 0.067)/2 or 0.022 inch is provided; and the resulting ratio (0.110/0.022) is five.

In addition, the Examiner states that the limitation of clam 27 of "an outer diameter of said cap at said engagement portion is approximately at least six times a wall thickness of said cap at said engagement portion" is not supported by the Specification and is new matter. This rejection is traversed.

At page 5, lines 20-23, dimensions are provided for the engagement portion of the cap:

> The engagement portion 18 has an outer diameter E of approximately 0.098 - 0.110 inch. The convex ring 20 defines an inner diameter F of approximately 0.067 – 0.078 inch. The engagement portion 18 has an inner diameter G 0.072 – 0.084 inch distal of the convex ring 20 (toward the lead-in portion 16) and a

> slightly smaller diameter H proximal of the ring 20 (toward the closed end 22), e.g., smaller by approximately 0.002 inch.

Using such dimensions, it can be calculated that a dimensional relationship supported by the Specification is an outer diameter E of 0.098 inch, and a radial wall thickness of, e.g., (0.098 – 0.072)/2 or 0.013 inch. This provides an outer diameter to radial wall thickness ratio of 7.53, meeting the "at least six times" claim limitation. Moreover, another dimensional relationship supported by the Specification is an outer diameter E of 0.110 inch, and a radial wall thickness of, e.g., (0.110 – 0.084)/2 or 0.013 inch, providing an outer diameter to radial wall thickness ratio of 8.46, also meeting the "at least six times" claim limitation. Since the claimed "at least six times" is well within the range shown above, (i.e., above five and below 8.46), it is not understood what statutory requirement under 35 U.S.C. § 112 exists for disclosing the benefit of claimed limitation. It is respectfully requested that the rejection be withdrawn.

Claims 1, 11 and 19 have been amended to obviate the rejection with respect to "pushing" the cap on the nail. The amended language indicates that the cap is placed on the nail and held by frictional engagement. This is supported at page 2, lines 15-18:

> [A] plastic cap is provided which is sized and shaped to facilitate placement over the cut end of a K-wire, orthopedic nail, or similar shaped device, and for frictional engagement on the device.

Claim 1 has also been amended to delete reference to the "orthopedic nail" being stiff. However, it is submitted that, by definition, an orthopedic nail is inherently stiff in order to support a bone fixation and/or fracture.

In view of the above, it is submitted that all written description rejections raised by the Examiner have been obviated.

Claims 1, 2, 4-7, 11-15, 19, 20 and 28 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,894,110 to Simmons et al. The applicant respectfully traverses the rejection for the following reasons.

In order to support a rejection of a claim under 35 U.S.C. § 102(b), "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Simmons reference cited by the Examiner fails to teach all of the elements of the claims. Claim 1, prior to any amendment, required a radiopaque composition. The examiner states that in view of the disclosure in the Specification he is interpreting the claimed radiopaque structure "as being any plastic capable of being combined with a radiopaque material." The basis of this rejection fails to meet the minimum requirement for maintaining a rejection on the basis of anticipation. A rejection cannot be maintained on the basis of Section 102 because a reference teaches something different but could physically be modified to meet the claimed invention. For a rejection under Section 102, the reference much teach all the elements of the claimed invention in as complete as detail as contained in the claim. The Examiner has not met his burden to support the rejection of the claims.

Moreover, there is no incentive to modify the Simmons wire nut connector, clearly not intended for any biological use, to include a radiopaque substance such that it is comprised of a radiopaque plastic material for viewing under fluoroscopy. Therefore, the Examiner also cannot meet the burden of establishing of prima facie case of obviousness under 35 U.S.C. § 103(a).

Furthermore, with respect to claims 5, the "lead-in portion" (identified by the examiner between the open end and reference numeral 16) is not cylindrical as required by the claim. From the two identified points, measurement indicates that the lead-in portion in Simmons tapers (from 29.5 mm and 27 mm in Fig. 2). In fact section 28 is "resilient skirt" (col. 3, line 7). As a skirt flares, it is not cylindrical. With respect to claim 6, it is also required that the engagement portion be cylindrical. The Examiner does not define the portion of Simmons which he believes corresponds to the "engagement portion", but assuming it is from the "lead-in portion" forward, it is noted that such portion also tapers in Simmons (from 27 mm to 23 mm before bump 26 in Fig. 2).

In view of the above, the Examiner has not met his burden of a rejection of claims 1, 2, 4-7, 11-15, 19, 20 and 28 under 35 U.S.C. § 102(b), and such claims should be indicated allowable over the cited art.

Claims 21-24 and 29 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,885,227 to Finalyson. The applicant respectfully traverses the rejection for the following reasons.

First, claim 21 requires a combination of a nail and a cap. The Examiner has identified the nail as element 12d. Element 12d is a portion of core 12 "tapered into an essentially flattened section." (Col. 3, lines 11-12, Table 1) Finlayson indicates that this provides bendability to the end of the guidewire. (Col. 3, lines 64-66) Clearly, this highly bendable flattened structure is not an orthopedic nail. An orthopedic nail is a limitation by definition. Such nail must have the stiffness to stabilize and support a fractured bone. The guidewire in Finlayson is designed for very high flexibility: "[it] must be thin and flexible enough to advance through small arteries within the coronary vasculature." (Col. 1, lines 12-13) It is clearly not capable for support in any orthopedic applications, has no such suitable structure, and is not an orthopedic nail. Nails of the type claimed include K-wires (Kirschner wires), identified in the Specification at page 2, lines 16-17, which provide the structure necessary for an orthopedic nail. As set forth at http://orthopedics.about.com/cs/brokenbones/g/kirschner.htm:

> A Kirschner wire is a thin, rigid wire that can be used to stabilize bone fragments. These wires can be drilled through the bone to hold the fragments in place. They are placed percutaneously (through the skin), thus avoiding an operation in some cases. In other cases, the K-wires are used after an operation to hold bone fragments in place. Also known as: K-Wire.

The flattened portion 12d, or any portion of highly flexible core 12, fails to meet the limitation of an orthopedic nail.

Second, claim 21 requires that the lead-in portion of the cap be spaced apart from the end of said nail by a "clearance". In Finlayson, the cap 20 is in direct contact with the core 12, and especially portion 12d along its entire length. However, the Examiner in the Response to Arguments, has indicated that nail is limited to portion 12d, and no other portion of core 12, to show that he is interpreting the reference so that there is a clearance between the proximal end of tip 20 and nail 12d. This is a disingenuous deconstruction of Finlayson, in which only flattened ultraflexible portion 12d, having a length of approximately 1.5 cm, is considered to be an orthopedic nail.

Furthermore, with respect to claim 22, the nail is required to have a "non-passivated cut end". This is not a "cutting end" in relation to how it "could cut tissue" (as misinterpreted by the Examiner), and the Examiner has maintained this mischaracterization from the prior office action even after the clear meaning has been identified and the clear error in interpretation has been brought to his attention. In fact, the cut end of the nail will be a trailing end of the nail after the nail is inserted and does not lead into the patient to perform any "cutting." As clearly set forth in the Specification, small diameter orthopedic nails, e.g., K-wires are often inserted into bones. Such nail is "passivated" to increase corrosion resistance and reduce reactivity in the human body. (Passivation, as is well-known in the art, creates a relatively non-reactive thin oxide film over the outer surface of the metal. See below.) However, such nail may need to be cut down in length during implantation which exposes a reactive non-passivated cut end of the nail to the body. It is this non-passivated cut portion of the nail over which the cap is

positioned. (Spec. at page 1, lines 10-18, page 2, lines 18-20) Finalyson fails to teach how the end of the flattened portion 12d is formed.

In the Response to Arguments, the Examiner states that one cannot determine whether nail 12d was passivated prior to placing cap 20, but concludes that the cap now is what passivates the "nail" 12d. Passivation is a term of art; it means:

> Immersion of stainless steel in a solution of nitric acid, or of nitric acid plus oxidizing salts, which restores the original corrosion resistant surface by forming a thin transparent oxide film. The treatment also dissolves any embedded or smeared iron picked up on the surface during processing. (See http://metals.about.com/od/metalterminology/l/bldefpassivatio.htm)

The cap may cover the end, but cannot passivate the end, as passivation is a metallurgical process that the cap cannot cause the nail to undergo.

Moreover, the Examiner also makes an argument in the Response to Arguments that nail 12d could "actively damage tissue while passive within the bumper coating cap (20)." This relevance of this point is not seen, as it is not claimed that the nail is used in a passive manner, does not damage tissue, or anything else relevant to this argument.

Claim 24 also requires a metal orthopedic nail having a cut end and a cap provided over the cut end of said nail. For reasons advanced above, Finlayson fails to teach or suggest the claimed invention.

In view of the above, the Examiner has not met the burden of a rejection of claims 21-24 and 29 under 35 U.S.C. § 102(b), and such claims should be indicated allowable over the cited art.

Claims 3, 8-10 and 16-18 are allowable as depending from claims allowable for reasons advanced above.

With respect to the Examiner's Response to Arguments, it is noted that the Examiner is taking an unreasonably broad interpretation of "metal orthopedic nail": "A relatively elongated and straight member than can be inserted into a member," again citing element 12d at the very end of the guidewire. It is inherent in the nature, substance, and structure of an orthopedic nail that it be capable of supporting a bone across a fracture. Regardless of whether the bendable flattened tip of a guidewire can be fed through the marrow of the medullary canal of a bone, it does not have the structure to support a bone across a fracture. Further, the Examiner's example that even "a piece of straw through telephone pole after a tornado is stiff" is indicative that the Examiner is not making "reasonably broad" interpretations. With such interpretations, words cease to have meaning. It is respectfully requested that the Examiner reconsider his approach and allow the claim terms to be interpreted in light of reasonable and commonly appreciated meanings of such words.

Finally, it is noted that the Examiner states that Finlayson indicates in his Abstract "that the tip may be may be stiffer or more flexible." Finlayson, however, is not referring

to the flattened section 12d, but rather the entire end of the guidewire which can be made stiffer or more flexible solely by selection of the material durometer of the plastic that covers the end of the guidewire. This offers no teaching or suggestion relevant to the claims. (See Abstract, lines 16-18.)

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

In the absence of an indication of allowability of the claims, it is requested that the Examiner **withdraw the finality of the rejection** to adequately address the claims where his burden and the statutory requirement clearly have not been med.

In the event the Examiner continues to maintain the rejection of the claims, it is still requested that the **amendment to the claims be entered to place the claims in better condition for appeal and limit the number of issues for appeal.**

Respectfully submitted,

David S. Jacobson
Reg. No. 39,235
Attorney for Applicant(s)

GORDON & JACOBSON, P.C.
60 Long Ridge Road, Suite 407
Stamford, CT 06902
Ph:(203) 323-1800
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